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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,871	06/20/2003	R. Glen Coleman	PD-170.02	6659
27581	7590	07/28/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			QADERI, RUNA S	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,871

Applicant(s)

COLEMAN, R. GLEN

Examiner

Runa S. Qaderi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/15/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION***Specification***

The disclosure is objected to because of the following informalities: In the specification the Cross-reference to related applications section recites "Serial No. 09/488,844 filed January 21,200, now US Patent No. 6,361,531" twice and each recitation is followed a different title of the patent. The second recitation is followed by the correct title of the 6,361,531 patent. Please delete the first recitation to correct for reiteration and title. Appropriate correction is required.

The abstract of the disclosure is objected to because it exceeds the 150-word limit. Correction is required. See MPEP § 608.01(b).

Double Patenting

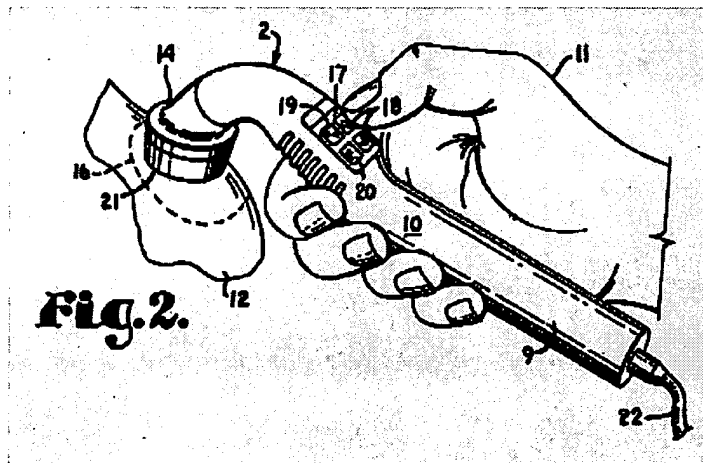
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 9-12, and 21-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,692,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are an obvious broadening of the patent claims.

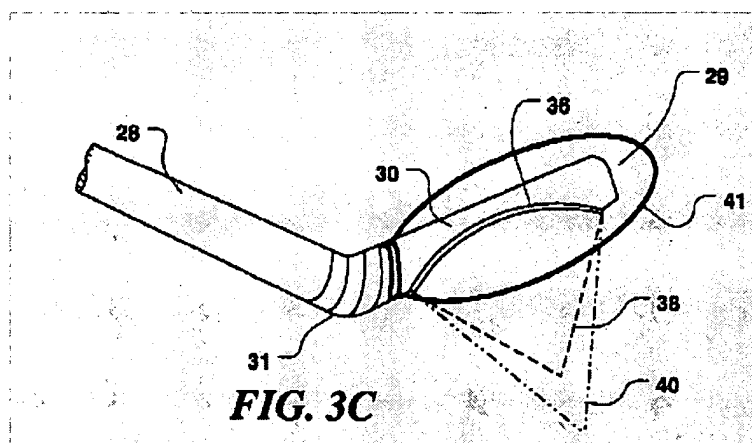
Claims 4, 6-8, 13, 16, 18-20, and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims



of U.S. Patent No. 6,692,450 in view of Castel (US 5,413,550). The patent claims disclose the claims of the present application except for the specifics of the handle of the ultrasound therapeutic device. Figure 2 of Castel above diagram the specifics of the handle as disclosed in applicant's claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the US patent 6,692,450 in view of Castel because the graspable handle with control switches or buttons allows for quicker and thus better control of the therapeutic procedure which is a well known expedient in the art.

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Claims 5 and 17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of U.S. Patent No. 6,692,450 in view of Weng et al. (US 6,626,855). The patent claims disclose



the claims of the present application except for the malleability of the handle shaft of the ultrasound therapeutic device. Figure 3C of Weng et al. above diagram the flexible portion 31 of the handle shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the US patent 6,692,450 in view of Weng et al. because the flexibility or malleability of the handle shaft allows for better maneuverability of the device to different regions of interest as taught by Weng et al.

Claim Objections

Claim 27 is objected to because of the following informalities: Claim 27 depends from claim 21; both claims are of different statutory class of inventions. Claim 27 is to an apparatus while claim 21 is to a method. For a claim to depend from another claim, both must belong to same statutory class of invention. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

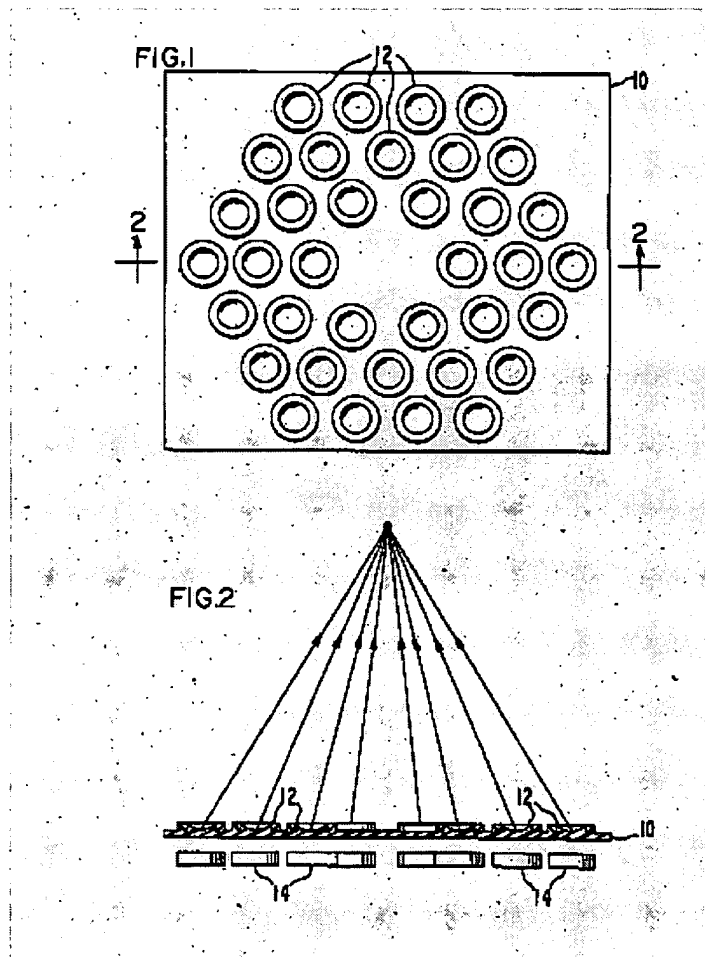
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,562, 900) in view of Linuma (US 5,448,994).

With regards to the rejected claims Anderson et al. discloses an apparatus and method of providing a lightweight, single piece tray of properly aligned transducer/lens elements for the usual treatment/diagnostic environment devices to simplify the procedure and improve of the quality of the treatment delivered to the patient. Figures 1 and 2 of Anderson et al. below diagram the system. An array of transducer/lens (14/12) are positioned in a generally rectangular tray 10 to provide for the focused ultrasound heat treatment, column 1 lines 11-13. With regards to the rejected claims 1 and 9 figures 1 and 2 of Anderson diagram ultrasound emitting member (14/12) spaced from one another along a row, such that ultrasound is emitted at a predetermined distance outwardly from an active surface. With respect to claim 1 Examiner interprets active surface as the surface in which the ultrasound waves are emitted from, according which is inherent in any ultrasound wave propagating device. With respect to claim 9 the active surface is interpreted as carrying one or more rows of spaced apart ultrasound emitting elements. Accordingly the holding frame for housing the tray of transducer/lens

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assembly as taught by Anderson et al. satisfies the active surface limitation of applicant's claim 9, column 1 lines 64-66.



With respect to claims 2, 10, and 14 the transducer elements of Anderson et al. satisfy the piezoelectric elements of the applicant by emitting ultrasound energy in response to an electric current supplied. With respect to claims 3 and 15, although Anderson et al. does not teach a curved transducer element, the transducer/lens assembly of Anderson et al. satisfies the function of providing a focused ultrasound treatment. Therefore it would have been obvious to provide either the curved transducer element or the transducer/lens assembly because they are functional equivalents. Regarding the

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claims Anderson et al. does not explicitly recite a handle. More specifically to claims 1.1 and 12 Anderson does not disclose the power supply and the control unit, respectively. Furthermore Anderson et al. does not teach selective actuation and de-actuation of the one or more transducer elements.

It is inherent or in the alternative obvious to one of ordinary skill in the art at the time the invention was made to provide for a handle such that maneuverability of the device is possible. A common definition of a handle is an appendage to an object such that the object can be moved or used. According to this definition a handle is inherent or in the alternative obvious such that the lightweight single piece tray of transducer/lens elements can be moved or used to provide the appropriate ultrasound treatment to the tissue.

It is inherent or in the alternative obvious to one of ordinary skill in the art at the time the invention was made to provide a power supply for generating an electric signal to actuate the elements thereby emitting ultrasound because a power supply is necessary for the functionality of the device. The treatment cannot be performed without the necessary power source.

Linuma teaches a system and method of ultrasound therapy comprising a control unit for selective actuation and de-actuation of the transducer elements to provide treatment to desired regions, column 6 lines 28-37. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Linuma with the teachings of Anderson thus satisfying the applicant's invention because it

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allows for better control of the therapy procedure to the desired area of the tissue as taught by linuma.

Claims 4, 6-8, 13, 16, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,562, 900) in view of linuma (US 5,448,994) as applied to claims 1 and 9 above, and further in view of Castel (US 5,413,550).

Anderson et al. in view of linuma disclose the claimed invention as discussed above except for the specifics of the handle of the ultrasound therapeutic device. Figure 2 of Castel above diagram the specifics of the handle as disclosed in applicant's claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the present invention via the combination of the Anderson et al. in view of linuma and further in view of Castel because the graspable handle with control switches or buttons allows for quicker and thus better control of the therapeutic procedure which is a well known expedient in the art.

Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,562, 900) in view of linuma (US 5,448,994) as applied to claims 1 and 9 above, and further in view of in view of Weng et al. (US 6,626,855).

Anderson et al. in view of linuma teach the present claimed invention as discussed above except for the malleability of the handle shaft of the ultrasound therapeutic device. Figure 3C of Weng et al. above diagram the flexible portion 31 of the handle shaft. It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to provide the present invention via the combination of Anderson et al. in view of linuma and further in view of Weng et al. because the flexibility or malleability of the handle shaft allows for better maneuverability of the device to different regions of interest as taught by Weng et al.

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (US 4,562, 900) in view of Castel (US 5,413,550).

With respect to 21 Anderson et al. teaches a method of ultrasound treatment to a tissue by heating the tissue. The lightweight tray of Anderson et al. holds an array of transducer/lens to be positioned adjacent to tissue of a patient. The transducers are actuated to provided focused ultrasound energy at a predetermined distance from the active surface, as shown in figure 2 of Anderson. The step of providing ultrasound treatment via the entire tray of transducer/lens elements of Anderson satisfies applicant's limitation to selecting and actuating one or more ultrasound emitting elements.

With respect to claims 22 and 23 although Anderson et al. does not explicitly recite the step of providing an electric current to actuate the transducer elements, it is inherent or in the alternative obvious to one of ordinary skill in the art at the time the invention was made to provide the step of an electric signal to actuate the elements thereby emitting ultrasound because this step is necessary for the method to be performed. The treatment cannot be performed without the necessary electric signal. Furthermore with respect to 24-26, Anderson et al. does not explicitly recite the desired dimensions or pattern of the tissue to be heat treated. On the same note the actuation or

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selection of the entire tray of transducer/lens assembly of Anderson et al. provides the method of targeting treating to any region of a tissue. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a method of treating various dimensions and patterns of desired tissue because the method of Anderson et al. is both capable and does not preclude from providing different focal points to provide treatment to any desired dimension or pattern of the tissue. In addition the dimensions of the treated tissue are dependant on the dimensions of the necrotic tissue to be heated.

In addition although, the term "ablation" of tissue is not present in the Anderson et al. reference, the teaching to "heat the target" includes or makes obvious ablation of the tissue. It would have been obvious for one of ordinary skill in the art at the time the invention was made to ablate the target tissue because the method of Anderson et al. does not preclude one from tissue ablation since the patent discloses ultrasound heating of target.

Finally the step of grasping a handle coupled to the ultrasound emitting member is not expressly taught in the Anderson et al. reference. The step of grasping would have been inherent such that the lightweight tray of transducer/lens assembly of Anderson et al. can be positioned adjacent to the target tissue. Or in the alternative the step of grasping is obvious in view of Castel. Figure 2 of Castel above diagram the step of grasping such that the handle is external to the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method

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of Anderson et al. with the method of Castel because the step of grasping handle allows for maneuverability of the lightweight tray assembly of Anderson et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 605-4285. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSQ

RSQ

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